DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

4091 '99 MAY -4 A10:10

Re: Femara™
Docket No.: 98E-0611

APR 29 1999

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,978,672, filed by Novartis Corp, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Femara™, the human drug product claimed by the patent.

The total length of the regulatory review period for Femara™ is 2,160 days. Of this time, 1,794 days occurred during the testing phase and 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 28, 1991.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on August 28, 1991.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: July 25, 1996.

   FDA has verified the applicant's claim that the new drug application (NDA) for Femara ™ (NDA 20-726) was initially submitted on July 25, 1996.

3. The date the application was approved: July 25, 1997.

   FDA has verified the applicant's claim that NDA 20-726 was approved on July 25, 1997.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Michael W. Glynn
Novartis Corp.
Patent Department
59 Route 10
East Hanover, NJ 07936-1080

DATE: APR 2 9 1999

TO: Sabrina Crisp, Regulations Policy and Management Staff, HF-26

From: Brian J. Malkin, Associate Director for Patents and Hearings, HFY-20

RE: Federal Register Notice Information for Femara™
Docket No. 98E-0611, FRDTS# OC99114

Attached is a FR Notice for the human drug product, Femara™. This document has been internally reviewed and cleared by OHA.

Please note that Femara™ is a trademark. Therefore, the superscript "TM" notation will be needed.

Please call me if you have any questions. My number is 827-6620 (Rm. 15-22).

Thank you for your assistance.

98E-0611

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

2505 '99 MAY -4 A9:48

Memorandum

Date: APR 29 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for Femara™

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned human drug product under the Docket Number **98E-0611** stating that this particular patent is eligible for regulatory review. The Patent Number is **4,978,672**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.